

MEMORANDUM

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RE: COVID-19 Update: FDA and TTB Response to Increased Demand for Alcohol-Based Hand Sanitizer Production

As the novel coronavirus crisis continues to escalate, the demand for hygienic products such as hand sanitizer has dramatically increased. In response, many businesses, such as food and industrial and beverage alcohol manufacturers, are seeking to produce alcohol-based hand sanitizers using certain food grade materials, or to produce alcohol to be used in production of such sanitizers. In recent days, federal agencies such as the Food and Drug Administration (“FDA”) and the Alcohol and Tobacco Tax and Trade Bureau (“TTB”) have relaxed certain regulatory requirements for the production of alcohol-based hand sanitizers, in part, to respond to the call for food grade materials in such hand sanitizer products.¹ This memorandum provides a brief overview of the recently issued guidance, reflecting updates made to the FDA policies as of March 27 and to the TTB policies as of March 26.²

FDA Guidance Documents

Late last week, FDA updated two guidance documents regarding the temporary manufacture of certain alcohol-based hand sanitizer products.³ The first (“Hand Sanitizer Guidance”) sets out the criteria under which FDA will exercise enforcement discretion for entities that are not currently licensed or registered drug manufacturers that would like to prepare alcohol-based hand sanitizers

¹ We note that hand sanitizer is regulated by FDA as an over-the-counter drug. While the Environmental Protection Agency (“EPA”) regulates cleaning products used to kill microbes on inanimate objects as “pesticides” under the Federal Insecticide, Fungicide, and Rodenticide Act, hand sanitizer is used to kill microbes on the human body. 7 U.S.C. § 136; 40 C.F.R. § 152.6(c); *see also* [Frequently Asked Questions about List N: Disinfectants for Use Against SARS-CoV-2 on EPA’s website](#).

² This memorandum is offered for general information and educational purposes. It is not offered as, intended as, and does not constitute legal advice. It is not intended to create, and receipt of it does not constitute, a lawyer-client relationship.

³ FDA has also issued guidance outlining the criteria under which the agency will exercise enforcement discretion for pharmacies and registered outsourcing facilities. *FDA Policy for Temporary Compounding of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency*, Immediately in Effect Guidance for Industry, March 2020, <https://www.fda.gov/media/136118/download>. We do not discuss this guidance in this memorandum.

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for consumer use and for use as health care personnel hand rubs.⁴ Under the policy, manufacturers will need to follow a specified formulation, register with FDA as a drug manufacturer and list the product as an over-the-counter (OTC) drug, use specific labeling, and follow certain manufacturing and testing practices. The second guidance document (“Alcohol Guidance”) relates to the manufacture of alcohol (ethanol) for incorporation in alcohol-based hand sanitizers.⁵

Importantly, under both guidance documents, FDA is requiring use of denatured alcohol for use in hand sanitizers. Further, FDA has authorized only specific formulas for denaturing the alcohol (i.e., rendering it bitter and unpalatable), but the revised guidance offers some greater flexibility in the permissible denaturing formulas, as compared with the prior version. Companies are encouraged to closely review the authorized denaturing formulas and consider submitting additional formulas to FDA for consideration.

FDA Guidance Document #1: Preparation of Alcohol-Based Hand Sanitizer Products

The guidance document states that FDA does not intend to take action against firms that prepare alcohol-based hand sanitizers for consumer use and for use as health care personnel hand rubs in the following circumstances.

1. The hand sanitizer is manufactured using only the following ingredients in the preparation of the product
 - a. (*Select one of two options*) (1) Alcohol (ethanol)⁶ that is not less than 94.9% ethanol by volume⁷; **OR** (2) Isopropyl Alcohol
 - b. Glycerin (glycerol) United States Pharmacopeia (USP) or Food Chemical Codex (FCC) (also known as “food grade”)
 - c. Hydrogen peroxide
 - d. Sterile water (e.g., by boiling, distillation, or other process that results in water that meets the specifications for Purified Water USP). Water should be used as quickly as possible after it is rendered sterile or purified.
2. The alcohol (ethanol) is denatured either by the alcohol producer or at the point of production of the finished hand sanitizer product.
 - a. FDA has, to date, authorized three formulas for denaturing alcohol for use in hand sanitizers. The specific formulas can be found in Appendix C to the “Alcohol Guidance” and are set out below. The guidance document allows the use of TTB Formula 40A or 40B with or without the tert-butyl alcohol. Note that the guidance characterizes 40B as the “preferred” formula, while 40A and 3C are considered alternatives, but any of these three is acceptable.
 - b. FDA states that it is continuing to evaluate other potential formulas, including the inclusion of acetone, for denaturing. FDA invites companies that wish to use different denaturants (bitterants) to contact FDA at COVID-19-hand-sanitizers@fda.hhs.gov.
 - c. The three currently authorized formulas are as follows:

⁴ *Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID-19), Guidance for Industry*, Updated March 27, 2020, <https://www.fda.gov/media/136289/download>.

⁵ *Temporary Policy for Manufacture of Alcohol for Incorporation Into Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID-19), Guidance for Industry*, Updated March 27, 2020, <https://www.fda.gov/media/136390/download>.

⁶ FDA notes that the alcohol must be manufactured either (1) using distillation and fermentation processes typically used for consumable goods, or (2) synthetically only if it meets USP or FCC grade.

⁷ FDA states, “Lower ethanol content alcohol falls within this policy so long as it is labeled accordingly and the finished hand sanitizer meets the ethanol volume to content concentration of 80%.”

Preferred Formula

27 CFR 21.76 Formula No. 40-B

To every 100 gallons of alcohol add:

One-sixteenth avoirdupois ounce of denatonium benzoate, N.F., and 1/8 gallon of tert-butyl alcohol

OR

To every 100 gallons of alcohol add:

One-sixteenth avoirdupois ounce of denatonium benzoate, N.F.

Alternative Formulas

27 CFR 21.75 Formula No. 40-A

To every 100 gallons of alcohol add:

One pound of sucrose octaacetate and 1/8 gallon of tert-butyl alcohol

OR

To every 100 gallons of alcohol add:

One pound of sucrose octaacetate

27 CFR 21.37 Formula No. 3-C

To every 100 gallons of alcohol add:

Five gallons of isopropyl alcohol

3. The hand sanitizer is manufactured according to the following formula:
 - a. Alcohol (ethanol) (80%, volume/volume (v/v)) in an aqueous solution; **or** Isopropyl Alcohol (75%, v/v) in an aqueous solution.
 - b. Glycerin (glycerol) (1.45% v/v).
 - c. Hydrogen peroxide (0.125% v/v).
 - d. Sterile distilled water or boiled cold water.
4. **The firm does not add other active or inactive ingredients, such as ingredients to improve the smell or taste, due to the risk of accidental ingestion in children. Different or additional ingredients may impact the quality and potency of the product.**
5. The firm pays particular attention to ensure the ethanol or isopropyl alcohol active ingredient is correct and the correct amount of the active ingredient is used. A simple record should be used to document key steps and controls to assure each batch matches the formula developed for the drug product.
6. The hand sanitizer is prepared under sanitary conditions and equipment utilized is well maintained and fit for this purpose.
7. The firm uses the most accurate method of analysis available at the site for verification of alcohol content in samples of the finished drug product before each batch is released for distribution. Methods can include gas chromatography (GC), alcoholmeter, hydrometer, or other chemical analysis of at least equivalent accuracy. The sample tested can be performed on in-process material before filling into the final containers to be distributed.
8. The hand sanitizer is labeled consistent with the labeling shown in the Appendices to the FDA guidance document.

9. Firms register their facility and list these products in the FDA Drug Registration and Listing System. The guidance document contains links to assist with registration. We note that this is a separate registration from the FDA food facility registration.

The policy is immediately effective and will be withdrawn once the public health emergency is over.

Note that the FDA guidance states that the formulation above is consistent with WHO recommendations⁸ but there are slight differences. To be eligible for the enforcement discretion, entities should follow the formulation set out in the FDA guidance.

The enforcement discretion is limited to only those products that meet the criteria outlined above. Manufacturers should consult the guidance document for full details on the requirements. Firms will also be expected to have a way to accept adverse event reports for any products they manufacture, and submit adverse event reports to FDA, as described further in the guidance.

FDA Guidance Document #2: Manufacture of Alcohol (Ethanol) for Incorporation in Alcohol-Based Hand Sanitizer Products

FDA states it does not intend to take action against alcohol production firms that manufacture alcohol (i.e., ethanol or ethyl alcohol) for use as the active pharmaceutical ingredient (API) in alcohol-based hand sanitizers for consumer use and for use as health care personnel hand rubs in the following circumstances.

1. As described above, the alcohol must be no less than 94.9% ethanol by volume, although FDA also states, “Lower ethanol content alcohol falls within this policy so long as it is labeled accordingly and the content is sufficient to enable the finished hand sanitizer to meet the ethanol concentration of 80% v/v.”
2. Any water used to adjust the finished ethanol content in the alcohol API is sterile.
3. The alcohol (ethanol) is denatured either by the alcohol producer or at the point of production of the finished hand sanitizer product. See the discussion of denaturing requirements above.
 - a. FDA explains, “Denaturing is critical because there have been reports of adverse events, including deaths, from unintentional ingestion of hand sanitizer, particularly in young children. ... the alcohol intended for incorporation into a finished product must be labeled accurately as ‘denatured’ or ‘undenatured’ accordingly.”
 - b. Similar to the first guidance document, FDA reiterates, **“Beyond alcohol, water, and denaturants (if added at the point of production), the alcohol production firm does not add other ingredients. Different or additional ingredients in the API may impact the quality and potency of the finished hand sanitizer product, and may increase the risk of accidental ingestion in children.”**
4. The alcohol production firm ensures the ethanol content in the finished API before being denatured is at least 94.9% by volume (or of sufficient content to enable the finished hand sanitizer to meet the ethanol concentration of 80% v/v).

⁸ WHO’s recommendations, titled “Guide to Local Production: WHO-recommended Handrub Formulations,” are available at https://www.who.int/gpsc/5may/Guide_to_Local_Production.pdf. The formulation for the ethanol product is 8333 mL of 96% ethanol, 417 mL of 3% hydrogen peroxide, and 145 mL of 98% glycerol while the isopropyl alcohol formulation is 7515 mL of 99.8% isopropyl alcohol, 417 mL of 3% hydrogen peroxide, and 145 mL of 98% glycerol.

- a. If the alcohol is to be distributed to another firm for producing the hand sanitizer, it is labeled with the ethanol content determined by an appropriate test so that the hand sanitizer can be reliably produced at the intended labeled strength. A simple record should be used to document key steps and controls.
5. The alcohol is prepared under sanitary conditions and equipment used is well maintained and fit for this purpose.
6. The alcohol production firm uses the most accurate method of analysis available at the site for verification of ethanol content in a sample before each batch is released for distribution or for use in producing the hand sanitizer. The guidance specifies appropriate test methods.
7. The alcohol, if distributed to other producers, is labeled according to the labeling in Appendices A and B of the guidance.
8. Alcohol production firms register their facility and list these products in the FDA Drug Registration and Listing System (DRLS). As noted above, this registration is different from that for food facilities.

FDA encourages alcohol production firms to submit any adverse event reports they receive to FDA.

The policy is immediately effective and will be withdrawn once the public health emergency is over.

TTB Guidance

TTB is the federal agency that regulates industrial, beverage, and non-beverage alcohol production and use. On March 18, 2020, TTB released guidance waiving certain provisions of the internal revenue laws concerning alcohol and providing certain exemptions and authorizations to previously permitted alcohol fuel plants (“AFP”) and beverage distilled spirits plants (“DSP”) who wish to produce ethanol-based hand sanitizers to address the demand for such products during this emergency. On March 26, 2020, TTB revised its prior guidance in response to the FDA guidance discussed above in order to:

- (1) supersede TTB’s prior guidance with regard to the authorized formula so as to be consistent with FDA’s guidance; and
- (2) exempt distilled spirits plants (DSPs) from the requirements to request approval from TTB to receive denatured or undenatured distilled spirits in bond from another DSP and to obtain additional bond coverage.

The revised TTB guidance now requires the use of denatured ethanol, consistent with the FDA guidance, whereas the previous TTB guidance referred to both denatured and undenatured ethanol. This guidance also restates the provisions of the original guidance (TTB G 2020-1) that remain unchanged.⁹ We summarize the TTB guidance below.

- **Permit Guidance**: AFPs and beverage DSPs are exempt from the requirement to obtain additional permits or bonds to manufacture hand sanitizer or to supply ethanol for use in the

⁹ TTB Public Guidance: [Production of Hand Sanitizer to Address the COVID-19 Pandemic](#), TTB G2020-1A, March 26, 2020. This memorandum does not cover the aspects of this guidance pertaining to state and local governments wishing to obtain tax-free alcohol, nor similar provisions concerning hospitals, blood banks, sanitariums, certain pathological laboratories, non-profit clinics, and qualifying educational institutions.

manufacture of hand sanitizer to other TTB permittees who are authorized to receive such distilled spirits.

- AFPs and beverage DSPs must continue to keep records of their operations as usual, including any operations undertaken under this guidance.
- **Tax Guidance:** Nonbeverage products made with ethanol, including hand sanitizer, are not subject to federal excise tax. TTB reiterates that the FDA guidance specifies the use of denaturants when compounding hand sanitizer.
- **Formula Guidance:** TTB has authorized the manufacturing of hand sanitizer products by industrial alcohol users and DSPs using the formulations described in the FDA Hand Sanitizer Guidance discussed above without first obtaining formula approval from TTB.
- **Guidance for Users of Industrial Alcohol:** Industrial alcohol user permittees are exempt from the requirement to request approval from TTB to increase the quantities of denatured ethanol that they may procure.¹⁰
- **Guidance Regarding Transfers in Bond:** TTB is exempting DSPs from the requirements to request prior approval from TTB when receiving denatured or undenatured distilled spirits from another DSP and obtaining additional bond coverage. Rather than submit such requests to TTB for approval, DSPs must maintain records of such receipts, which would include records of the information currently required on TTB Form 5100.16.

Any existing AFP or DSP permittees can immediately commence production of hand sanitizer or ethanol for use in hand sanitizer, as described above, without having to obtain authorization from TTB. If a company is not already an AFP or DSP permittee, it must still apply for a permit from TTB to obtain denatured alcohol from a DSP to manufacture hand sanitizer or to obtain undenatured alcohol from a DSP, denature it, and then make hand sanitizer. In either case, the company would also need to meet the criteria in the FDA guidance outlined above in order to be eligible for the FDA enforcement discretion.

TTB's guidance is initially approved through June 30, 2020 with the possibility for extensions as necessary. It remains illegal under federal law to distill ethanol without a permit from TTB.¹¹

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We will continue to monitor this rapidly developing situation. If you need assistance, please don't hesitate to contact us.

¹⁰ See 27 C.F.R. §§ 20.42(a)(3) and 20.56.

¹¹ 26 U.S.C. § 5601.